Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK GMP 23083 Insp GMP 23083/22336157-0002 [V]

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER*(1),(2)*

Part 1

Issued following an inspection in accordance with :
Regulation 5 of the current Veterinary Medicines Regulations

The competent authority of United Kingdom confirms the following :

The Manufacturer : QILU PHARMACEUTICAL CO. LIMITED

Site address : QILU PHARMACEUTICAL CO. LIMITED, 8888 LVYOU ROAD, HIGH-TECH ZONE, JINAN, CN-250104, CHINA

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Regulation 5 of The current Veterinary Medicines Regulations

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 15/09/2025, it is considered that it complies with

- The principles and guidelines of Good Manufacturing Practice laid down in Regulation 5 of the current Veterinary Medicines Regulations

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in MHRA-GMDP. If it does not appear, please contact the issuing authority.

- *(1) Guidance on the interpretation of this template can be found in the Help menu of MHRA-GMDP database.*
- *(2) These requirements fulfil the GMP recommendations of WHO.*

Part 2

Veterinary Medicinal Products

1. MANUFACTURING OPERATIONS

[1.1] Sterile Products

[1.1.1] Aseptically prepared (processing operations for the following dosage forms)

[1.1.1.4] Small volume liquids

[1.2] Non-sterile products

[1.2.1] Non-Sterile Products (processing operations for the following dosage forms)

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[1.2.1.13] Tablets

[1.3] Biological medicinal products

[1.3.1] Biological medicinal products

[1.3.1.5] Biotechnology products

[1.4] Other products or manufacturing activity

[1.4.1] Manufacture of:

[1.4.1.3] Other

Biological active starting materials, MCB and WCB manufacture and storage

[1.4.2] Sterilisation of active substances/excipients/finished products:

[1.4.2.1] Filtration

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.13] Tablets

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

[1.6.4] Biological

Restrictions or Remarks

This inspection included the following workshops:
WS3200: Ranibizumab MCB/WCB and drug substance manufacturing (line 3210)
WS3400: Bevacizumab MCB/WCB and drug substance manufacturing (line 3430)
WS3300: Ranibizumab and Bevacizumab drug product manufacturing (lines 3310, 3320 and 3330)
WS6200: Abiraterone tablet manufacturing

26/01/2026	Name and signature of the authorised person of the Competent Authority of United Kingdom Confidential Medicines and Healthcare products Regulatory Agency Tel : Confidential

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